Title:	Number: 00-000-142-01	Revision Number: 3	Effective Date: 6/15/96
Corrective &Preventive Action	Prepared by:	Approved by:	Page :
	Sondra D. Gutkind	Sondra D. Gutkind	1 of 7

14.0 PURPOSE

To describe the requirements for implementing corrective and preventive action to eliminate the causes of actual or potential nonconformities.

14.1 SCOPE

This procedure will cover corrective actions for nonconforming products, internal audits, customer complaints, out of calibration equipment, and other related quality issues. *This procedure may be supplemented by a Pilot Program corrective and preventive action procedure that meets the requirements of ISO 9001-1994 and does not change the basic intent of this Division quality procedure.*

14.2 **Definitions**

- 14.2.1 Corrective or Preventive Action Process: An investigative process used to determine the root cause of problems or potential problems reported on the Corrective Action Request Form (CAR Form).
 - 14.2.1.1 Corrective Action Process: A process to provide for effective corrective action to eliminate problems and to prevent the recurrence of nonconformances.
 - 14.2.1.2 Preventive Action Process: A process to provide for effective preventive action to eliminate potential failures of the quality system and to preclude the occurrence of nonconformities and to initiate actions that will improve the product or quality system functioning.
- 14.2.2 Corrective Action Request (CAR): A written request used to report, initiate and track the corrective action and preventive action processes.

Title:	Number: 00-0000-142-01	Revision Number: 3	Effective Date: 6/15/96
Corrective &Preventive Action	Prepared by:	Approved by:	Page :
	Sondra D. Gutkind	Sondra D. Gutkind	2 of 7

- 14.2.3 Corrective Action Coordinator (CAC): An authority defined by the Division ISO Program Manager (DISOPM) or Pilot Program Department Head (PPDH) or designee as the point of contact for applicable CARs.
- 14.2.4 Actionee: Designated individual assigned by DISOPM or PPDH or designee to identify the non-conformance and to develop the course of action to correct or prevent the non-conformance from occurring.
- 14.2.5 Corrective Action Plan: When needed and where applicable, a plan to eliminate the problem or potential problem identified on the CAR Form.
- 14.2.6 Objective Evidence: Collected data that verifies that the corrective or preventive action was implemented.

14.3 RESPONSIBILITY

- 14.**3.1** The Division ISO Program Manager (DISOPM), or designee, and the Pilot Program Department Heads (PPDH), or designees, will be responsible for implementation of this procedure.
- 14.**3.2** Originators of Corrective Action Requests (CAR) will be responsible for providing a description of the nonconformity, customer complaint, or preventive action to be addressed.
- 14.3.3 The Corrective Action Coordinator (CAC) is responsible for assigning the CAR to the appropriate Responsible Manager or designee, for assuring that all CARs have been completed and for ensuring that the corrective/preventive action process is effective. They are appointed by the Pilot Program Department Head or designee at the Pilot Program level and by the DISOPM at the Division Level.

Title:	Number: 00-0000-142-01	Revision Number: 3	Effective Date: 6/15/96
Corrective &Preventive Action	Prepared by:	Approved by:	Page :
	Sondra D. Gutkind	Sondra D. Gutkind	3 of 7

- 14.3.4 The Responsible Manager is identified by the Corrective Action Coordinator (CAC) as the manager who is accountable for the corrective and/or preventive action. This person assigns an actionee to investigate and report on the CAR. He or she will review CARs for opportunities for improvements to products/services or to quality system operations.
- 14.3.5 The Actionee is assigned by the responsible manager to conduct the investigation, to determine the root cause and to define and implement the corrective and/or preventive actions that will be taken to eliminate recurrence of the problem.

14.4 PROCEDURES

- 14.**4.1** A Corrective Action or Preventive Action Request may be initiated to correct actual or potential deficiencies on:
 - Product equipment.
 - Reports.
 - Procedures or process implementation.
 - Data.
 - Quality system compliance.
 - **Significant and/or repetitive** customer complaints
 - Significant and/or repetitive nonconformances
 - Preventive actions which need to be addressed.
 - Other related quality issues.
- 14.**4.2** Actual and potential non-conformities shall be identified, and their investigation and the resulting corrective or preventive action for them conducted through the Corrective Action Request (CAR) system.

Title:	Number: 00-0000-142-01	Revision Number: 3	Effective Date: 6/15/96
Corrective &Preventive Action	Prepared by:	Approved by:	Page :
	Sondra D. Gutkind	Sondra D. Gutkind	4 of 7

- 14.4.3 CAR's may be initiated by any Pilot Program employee through use of CAR Form 00-0000-142-01A
- 14.4.4 Division personnel involved with the Pilot Program(s) may also initiate CAR's.
- 14.4.5 The originator describes the condition on a CAR form and submits it to the affected Pilot Program or Division CAC.
- 14.4.6 The CAC performs an analysis and evaluates the CARs which are applicable to his/her Pilot Program and determines acceptance into the CAR process.
- 14.4.7 The CAC assigns a control number to the CARs that are accepted into the CAR process, enters it into a log and submits a copy of the CAR to the DISOPM upon request.
- 14.**4.8** CAR's should be numbered in the following format:

XXXX-XXXXX

- 14.**4.8**.1 The first 4 digits are the Directorate, Department, Branch, and Section code designators.
- 14.**4.8**.2 The last 5 digits: the first 2 digits of this number identify the **fiscal** year (e.g. 95) and the last 3 digits are the enumerating number (001, 002).
- 14.**4.9** The Corrective Action Coordinator may ask the PPDH or designee and/or DISOPM or designee to close corrective actions or reject them based on their assessment of the corrective action's accuracy and applicability to the system. This is intended to improve the efficiency of the system and to maintain CAR focus on system issues.

Title:	Number: 00-0000-142-01	Revision Number: 3	Effective Date: 6/15/96
Corrective &Preventive Action	Prepared by:	Approved by:	Page :
	Sondra D. Gutkind	Sondra D. Gutkind	5 of 7

- 14.**4.9.1 The CAC replies to** rejected CAR's **and CARs** will be maintained on file and be available for review during internal audits of the internal audit and/or corrective action system.
- 14.**4.10** Several CARs with the same **basic condition** may be grouped together for **root cause** analysis of corrective action & follow up. These groupings will be the responsibility of the Corrective Action Coordinator(s).
- 14.4.11 The CAC assigns a Responsible Manager to be accountable for and take action on the CAR.
- 14.4.12 The Responsible Manager identifies an actionee who is best suited for finding the non-conformance and developing the corrective and/or preventive action to eliminate the re-occurrence of the nonconformance and prevent recurrence.
- 14.4.13 The actionee is responsible for determining the root cause, developing the corrective action to eliminate cause and/or preventive action to prevent potential problems, determining the implementation time schedule to complete the Corrective Action Request and implementing the corrective/preventive action.
 - 14.4.13.1 The corrective action should address any immediate needs that may be required to limit damage or liability associated with the CAR.
 - 14.4.13.2 In order to complete this assignment, the Actionee:
 - -Collects data and/or samples as appropriate
 - -Documents results of the root cause investigation
 - -Identifies actions needed to avoid and prevent future incidents.
 - -Identifies any needed system changes

Title:	Number: 00-0000-142-01	Revision Number: 3	Effective Date: 6/15/96
Corrective &Preventive Action	Prepared by:	Approved by:	Page :
	Sondra D. Gutkind	Sondra D. Gutkind	6 of 7

- -Determines timing and responsibilities for implementation of corrective/preventive action.
- -Records nonconformances that are dispositioned
- 14.4.14 The actionee submits the proposed corrective/preventive actions to be taken on the CAR to the Responsible Manager.
- 14.4.15 The Responsible Manager reviews the proposed corrective/preventive action for completeness and approves for acceptance and implementation.
- 14.4.16 After approval, completion and implementation, the Responsible Manger submits the CAR to the CAC.
- 14.**4.17** All completed CARs are to be sent to the DISOPM upon request for review and summation reporting for Management Review, Pilot Programs are to keep a copy of the applicable completed CARs.
- 14.**4.18** Completed CAR's are quality records, and will be retained for at least 2 years. The Corrective Action Coordinator will maintain these records. Pilot Program CAR's will be maintained at the applicable Pilot Program; Division CARs will be maintained at Division.
- 14.**4.19** All completed corrective actions will be verified for implementation and effectiveness by the individual assigned by the Corrective Action Coordinator and Documentation will be maintained within each Pilot Program for completion of the Corrective Action Process.
- 14.4.20 The Corrective Action Coordinator assigns a verifier who will verify that the CAR has been completed and is acceptable.

Title:	Number: 00-000-142-01	Revision Number: 3	Effective Date: 6/15/96
Corrective &Preventive Action	Prepared by:	Approved by:	Page :
	Sondra D. Gutkind	Sondra D. Gutkind	7 of 7

- 14.4.21 The CAC will ensure that the verifier has closed out the CAR and provides objective evidence that the corrective or preventive action is implemented and effective.
- 14.**4.22** Upon review **of the completed action**, if the corrective action is unacceptable, the CAR shall be returned to assigned personnel for further action.
- 14.**4.23** The Corrective Action Coordinator will be responsible for tracking, analyzing, and reporting on Pilot Program level CAR's.
- 14.**4.24** The DISOPM or designee will be responsible for tracking, analyzing, and reporting on Division level CAR's, and integrating Pilot Program CAR analysis **for management reviews when requested and/or appropriate**.
- 14.**4.25** Preventive action will also be taken on an ongoing basis by management to continuously improve the process. Management Reviews and internal auditing will be a part of this process. Preventive action will be to the extent warranted by the risks involved.

14.5 RECORDS

- 14.5.1 Corrective Action Request Form #00-0000-142-01A
- 14.5.2 Supporting Documentation (e.g. memos, revised procedures, copies of data, etc.).

14.6 ATTACHMENTS

- 14.6.1 Corrective Action Request Form #00-0000-142-01A
- 14.6.2 CAR Form Instruction Sheet